EXHIBIT 40

Anesthesia & Analgesia

Patient Warming Excess Heat: Effects on OR Ventilation Performance During Total Knee Replacement

--Manuscript Draft--

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Abstract:	Background: Patient warming has become a standard of care for the prevention of unintentional hypothermia based upon benefits established in general surgery. However, these benefits may not fully translate to contamination sensitive surgery (i.e. implants), for patient warming devices release excess heat that may disrupt the intended ceiling-to-floor ventilation airflows and expose the surgical site to added contamination. Therefore, we studied the effects of two popular patient warming technologies, forced air and conductive fabric, versus control conditions on ventilation performance in an orthopedic operating room during a simulated total knee replacement. Methods: Ventilation performance was assessed by releasing neutrally buoyant detergent bubbles ("bubbles") into the non-sterile region under the head-side of the anesthesia drape. We then tracked whether the excess heat from upper-body patient warming mobilized the "bubbles" into the surgical site. Formally, a randomized replicated design assessed the effect of device (forced air, conductive fabric, control) and anesthesia drape height (low-drape, high-drape) on the number of "bubbles" photographed over the surgical site. Results: The direct mass-flow exhaust from forced air warming generated hot-air convection currents that mobilized "bubbles" over the anesthesia drape and into the surgical site, resulting in a significant increase in bubble counts for the factor of patient warming device ($p<0.01$): forced air had an average count of 132.5 versus 0.48 for conductive fabric ($p<0.01$) and 0.01 for control conditions ($p<0.01$) across both drape heights. Differences in average bubble counts across both drape heights were insignificant between conductive fabric and control conditions ($p=0.87$). The factor of drape height had no significant effect ($p=0.94$) on bubble counts. Conclusions: Excess heat from forced air warming represents a significant ventilation

	disruption concern during orthopedic surgery. The use of thermally efficient patient warming devices (i.e. conductive) - those that minimize excess heat release - may be preferable for contamination sensitive surgery. The clinical impact of these findings should be subject to further trials involving infection-based endpoints.
Response to Reviewers:	*****We have included a formatted version of our response in the manuscript file. We recommend reading that version since there is a table or two and a couple of references included********** Response to Reviewer Comments: General Response to "Overall" Comments: (responses to specific comments after) We wanted to, first, thank everyone for their careful consideration and insightful comments regarding our study of patient warming and OR ventilation disruption. We acknowledge that the manuscript addresses an issue of contention among the anaesthesia community: the association between patient warming excess heat and operating room ventilation performance. We also realize the potential impact of this research on practice, given the wide-spread adoption of forced air warming during surgery. Our intention is not to disparage the use of forced air warming in general surgery: forced air warming has become a standard of care for the prevention of surgical hypothermia based upon well-established clinical benefits. We are, however, concerned about the potential effect of forced air warming during specialized procedures involving implantable materials. This is because implantable materials have an elevated susceptibility to airborne contamination-derived infection. At present, the most recent articles published on patient warming excess heat and ventilation disruption come to contradictory conclusions and highlight the need for further study. Two recent studies, undertaken in the United Kingdom, have characterized the thermal basis1¬ and airflow patterns2 supporting the physics behind ventilation disruption in laminar flow ORs. Further, the latter study found a significant association between the use of thermally inefficient patient warming systems (i.e. forced-air) and deep joint infection rates during hip and knee prothesis.2 In contrast, research undertaken in the Netherlands3 (recently published in the present journal) found no evidence of ventilation disruption due to forced air warming excess heat when evaluated with the DIN 1946-4:2008-12 standard.4 The exact reason(s) for these discrepancies is presently unknown, but there are significant differences between the study test methods that are worth exploring. The most relevant differences between these methods are twofold: 1) the challenge particulate location/methods and 2) the placement of the surgical lighting. First, the particle challenge method specified by the DIN standard involves the generation of a tracer aerosol dispersed from 6 locations. For evaluating the protection from outside loads, the DIN standard specifies 6 locations that comprise the corners and two sides of the outer ventilation boundary. For evaluating the protection from inside loads, the DIN standard specifies 6 locations that comprise the corners of the outer ventilation boundary and two interior locations next to the side of the operating room table. Thus, the DIN standard specifies 2 separate tests: 1) for outside load protective effect and 2) for inside load protective effect. It is presently unclear whether the study conducted in the Netherland3 tested the outside or inside protective effect since the study did not clearly specify this important distinction in the methods. Neither were separate values reported in the results for both inside and outside protective effect (as required by the DIN standard). In contrast, the United Kingdom study2 of airflow patterns assessed the effect of inside loads on the theatre ventilation using neutrally buoyant detergent bubbles in place of the tracer aerosol challenge. Inside loads were assessed in this study from 2 locations: 1) under the anaesthesia drape near the patient's head, and 2) adjacent to the operating table in a similar manner as recommended by the DIN standard for inside loads. Such broad differences in the location of the tracer challenge are one possible explanation for the different results. A second possible explanation for the differing study outcomes relates to surgical light positioning. The lighting arrangement specified by the DIN standard places the lights to the side of the operating table over the heads of the personnel. This was the arrangement tested in the Netherlands3 study. In contrast, common clinical practice in the United Kingdom studyx dictated that the lights be placed in-line with the surgical

table. Given that surgical lighting is often the most significant source of ventilation disruption in the operating theater – each light has a "flow shadow" extending 1 meter downstream of its body,5 differences in lighting placement affect the "flow shadow" regions which in turn change the dynamics of thermal air currents. As such, there is reason to believe that differences in lighting position could also be a contributing factor.

Thus, we feel that the present study is timely and warranted because it offers one additional data point regarding the potential association between patient warming excess heat and operating room ventilation performance. The overall debate on this topic has yet to be decided and, therefore, it is important that additional information be presented on the prevalence and scope of the association. In our opinion, this study attempts to do so by evaluating the effects of patient warming excess heat on ventilation performance in regards to inside particle loads. We do so with the standard draping and lighting arrangement used in clinical practice at a major tertiary medical center. Additionally, this study provides clinically relevant information on the specific effects of a given surgical setup and ventilation system on the phenomenon of interest. We feel that this represents important information in regards to the active debate given that variation in surgical procedures and practices (both across hospitals and countries) has hampered a successful resolution of the issue.

Lastly, a common suggestion expressed by the reviewers has revolved around expanding the scope of the study to include additional test data pertaining to: 1)the investigation of potential solutions to the problem of forced air warming ventilation disruption and 2) the use of further test configurations involving instrument trays and additional surgical staff. Although there is a clear and demonstrated need for such research, we are of the opinion that this is future research that would warrant its own independent manuscript. This is because the aims of the present manuscript were limited to investigating whether a ventilation disruption concern even exists for orthopedics at a tertiary medical center. Our intention was to investigate and identify the existence/nature of such problems with the intention of providing the building blocks for future research down the avenues suggested in the reviewers' comments.

1. Dasari K.B, Albrecht M, Harper M. Effect of forced air warming on operating theatre laminar flow ventilation performance. Anaesthesia. 2011 "In Press (accepted October 14th, MS# 6983)".

2. McGovern PD, Albrecht M, G Belani K, Nachtsheim C, Partington PF, Carluke I, et al. Forced-air warming and ultra-clean ventilation do not mix: An investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics. J Bone Joint Surg Br. 2011 Nov;93(11):1537–44.

3. Sessler DI, Olmsted RN, Kuelpmann R. Forced-Air Warming Does Not Worsen Air Quality in Laminar Flow Operating Rooms. Anesthesia and Analgesia [Internet]. 2011 Sep 29 [cited 2011 Nov 16];Available from: http://www.ncbi.nlm.nih.gov/pubmed/21965373

4. Deutsches Institut fu" r Normung (DIN). Annex C: determining the degree of protection. Ventilation and air conditioning. Part 4. VAC systems in buildings and rooms used in the health care sector (DIN 1946-4:2008-12). Dec 2008:1–67

5. Whyte W, Shaw BH. The effect of obstructions and thermals in laminar-flow systems. J Hyg (Lond). 1974 Jun;72(3):415-423.

Reviewer #1: This manuscript uses a simulated operating room set-up to compare ventilation characterisitics resulting from forced air and covection warmer devices. The authors found significant differences between the bubble patterns of the two devices. They speculate from their results that the forced air system could cause more wound infections. However, the authors do not provide any possible solutions to reduce the problems associated with the forced air system. Since forced air systems are in common use it is important that the authors propose and test a solution. They also need to emphasize that their study is a laboratory exercise and that no clinical conclusions can be reached.

Comments addressing the points raised here are listed in the general response above, with the exception of the last remark. In regards to whether the results of this laboratory exercise have clinical implications, we are of the belief that the observed ventilation disruption represents a potential contaminant mobilization concern that warrants attention. This is based upon the findings of the United Kingdom study1 where identical forms of ventilation disruption were associated with increases in infection risk for total knee and hip replacement. We do, however, agree that there were no infection rate endpoints in the present study and this distinction should be more prominent in the discussion. We, also, agree that the words "ventilation disruption" and "contaminant mobilization" are used interchangeably throughout the discussion. This is not accurate since we studied "ventilation disruption" using a tracer bubbles and not the actual mobilization of pathogenic contaminants. Therefore, we will tighten up the wording throughout to reflect these two points.

1. McGovern PD, Albrecht M, G Belani K, Nachtsheim C, Partington PF, Carluke I, et al. Forced-air warming and ultra-clean ventilation do not mix: An investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics. J Bone Joint Surg Br. 2011 Nov;93(11):1537–44.

The discussion should be shortened

Agreed, upon a second reading we decided to eliminate the section discussing forced air warming filtration since this material is outside the scope of the present study. We also added content regarding the discrepancy between studies identified in the general comments.

Specific comments
Page 6 - Line 30 - High intensity light - Did this light affect the heat currents?

The lighting (main heat source) was positioned well outside the ventilation field and focused into a thin plane cast from afar onto the drape. Given that the control conditions had no upward "bubble" mobilization and the outside location of the light body, the lighting appeared to have no significant thermal effect in the region of interest.

Page 6 - Line 36 - Helium - mixed air - what was the percentage of Helium?

The bubble generator actually takes two gas lines: 1) an input of pure helium (>99.97%), and; 2) an input of compressed air. The bubble generator uses an annulus to fill the bubbles with pure helium and employs an airstream of compressed air to convey them through the system. The amount of helium is exactly that required to offset the weight of the soap film bubble wall. Thus, the wording "helium mixed air" is not accurately representative, and we have made changes to the manuscript to reflect this.

Just a further point if you are interested. The bubble generator creates a varying distribution of helium filled bubble sizes that are fed into a centrifugal classifier. This classifier then discards any bubbles that are not "neutrally buoyant." It performs this action by swirling them in a well-defined circular motion: only bubbles having the correct size are passed through the system.

Page 7 - Line 4 - Occlusive clothing - What is occlusive clothing?

Occlusive clothing is just standard operating room dress (scrubs, masks, and hair bonnet). Manuscript changed to reflect this point.

Page 8 - Line 7 - Control - Better define the control group

Control: redefined as "control (no device)"

Page 8 - Line 12 - A Poisson regression - why was a Poisson model used? Did they

anticipate skewed data?

Yes, the data is skewed since many of the counts were close to zero; this is because negative values are not a possibility. The assumptions of normality only hold for count data when the mean number of counts is large (i.e. far from zero). Thus, standard linear regression techniques could not be employed in this study and, instead, a generalized linear model was used having a log-link for the canonical parameter. This is what constitutes the definition of a Poisson regression model, which is the typical method for dealing with count data having means near zero.

Page 9 - Line 9 - "elevation" – increase

Agreed.

Page 12 - Lines 4-5 - "below each light" What were the sizes of each light? Were they turned on and producing heat? Were they lights designed for use in a laminar flow field, i.e. small profile?

The surgical light model was Berchtold Chromophare D650 Plus and there were 2 lights in the OR. These are halogen bulb lights with a body diameter of 65cm (2.13 ft). Per the manufacturer's website, these lights are indicated for use during orthopedic procedures, but there is no indication as to whether they are specifically design for laminar flow environments. The body diameter of the lights are similar to those of competitors' lights for similar applications (i.e. Stryker visum 600 surgical light, body diameter of 60 cm (2 ft)). The lighting was turned off during all experiments to allow for visualization of the bubbles with the light curtain. Thus, there was no additional heat load due to lighting. This, however, tends to improve the performance of the ventilation system and, therefore, our results should be conservative in nature. These details were added to the manuscript.

Page 12 - Lines 40 - 57 - This paragraph is important since it quotes a paper on the same subject. Were the warming devices equivalent to those used in this study?

Yes, the warming blankets were identical to those used in the UK study: both torso blankets. The controllers were also identical to those used in the UK study.

Page 14 - Lines 49 - 57 - Is it possible that other reasons might explain why there were differences between historical and current studies? Please discuss

Differences between historical and current studies on laminar flow infection rates could be the result of any number of factors: study design (randomized versus observational), changes in infection reporting procedures, shift in patient demographics, emergence of new bacteria strains, changes in surgical practice, changes in prophylaxis measures, etc… However, one would typically expect improvements over time in the continuum of surgical care. Such improvements – other than those related to reporting procedures – would be expected to enhance the effectiveness of laminar flow ventilation in regards to reducing implant infection rates. This appears not to be the case nor are there any apparent answers to date that resolve this issue.

As such, some authors have come to the conclusion that laminar ventilation is fundamentally ineffective as a therapy, but in our opinion such claims are likely flawed. First, to date, there has been only one randomized clinical trial studying the efficacy of laminar flow. This trial found a significant reduction in implant infection rates for those procedures carried out in laminar flow ventilation versus turbulent ventilation operating rooms.1 Second, studies with relevant airborne bacterial contamination based endpoints (such as wound wash out bacteria counts) have shown a clear difference between laminar and turbulent ventilation.2 Thus, the underlying mechanism of laminar flow as a surgical intervention is supported, for it offers protection of the surgical site from airborne contaminants and, therefore, should reduce infection risk.

The troubling matter is that recent observational follow-on studies in the 1990's and 2000's,3-6 often national in scope, have not confirmed the clinically-established

benefits of laminar flow from the 1970's.1 Therefore, in our opinion the most likely explanation revolves around significant changes in surgical practice between the years 1980 and 2000 that have the potential to affect the performance of laminar flow ventilation. One change in surgical practice that correlates well with the observed failure of laminar flow is the wide-spread adoption of forced air warming in the 1980's and 1990's. Thus, the results of the present study and the one conducted in the UK6 provide a cause for concern, for they identify forced air warming excess heat as a ventilation disruption factor. By no means are we suggesting a definitive link, but there is enough information at hand to suggest an association based upon observations across multiple studies.

1. Lidwell OM, Elson RA, Lowbury EJ, Whyte W, Blowers R, Stanley SJ, et al. Ultraclean air and antibiotics for prevention of postoperative infection. A multicenter study of 8,052 joint replacement operations. Acta Orthop Scand. 1987 Feb;58(1):4-13.

2. Lidwell OM. Air, antibiotics and sepsis in replacement joints. J. Hosp. Infect. 1988 May;11 Suppl C:18-40.

3. Hooper GJ, Rothwell AG, Frampton C, Wyatt MC. Does the use of laminar flow and space suits reduce early deep infection after total hip and knee replacement?: THE TEN-YEAR RESULTS OF THE NEW ZEALAND JOINT REGISTRY. J Bone Joint Surg Br. 2011 Jan;93(1):85-90.

4. Miner AL, Losina E, Katz JN, Fossel AH, Platt R. Deep infection after total knee replacement: impact of laminar airflow systems and body exhaust suits in the modern operating room. Infect Control Hosp Epidemiol. 2007 Feb;28(2):222-226.

5. Brandt C, Hott U, Sohr D, Daschner F, Gastmeier P, Rüden H. Operating room ventilation with laminar airflow shows no protective effect on the surgical site infection rate in orthopedic and abdominal surgery. Ann. Surg. 2008 Nov;248(5):695-700.

6. McGovern PD, Albrecht M, G Belani K, Nachtsheim C, Partington PF, Carluke I, et al. Forced-air warming and ultra-clean ventilation do not mix: An investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics. J Bone Joint Surg Br. 2011 Nov;93(11):1537–44.

Reviewer #2:
General comments:
This is an interesting technical communication which might affect patient safety and recommendations for the use of devices for perioperative patient warming. I would, however, address some aspects regarding the study design and the presentation of the results.
I would suggest the authors perform additional airflow visualization procedures with a surgical team and instruments close to the surgical site. I would also perform a larger number of runs for each setting.

The surgical team comments are addressed above in the "general" comments. In terms of added runs for each setting, when the study rejects the null hypothesis (i.e. that all factor combinations had the same effect on bubble count) study powering is not an issue; power is only an issue when the study fails to reject the null hypothesis since there may have been insufficient data to discriminate between the null and alternative hypothesis. Further, additional runs would only be warranted if the study failed to reject the null and was deemed underpowered to detect the difference of interest. However, we did reject the null hypothesis, so no additional data points are required to support the conclusions of the study.

Detailed comments:
Abstract:
Page 3 line 8: Please delete "surgical". "unintentional" hypothermia might be correct.

Agreed

Page 3 lines 51-54: To my mind, the results of the study do not justify such a generalized statement. Please substitute "is recommended" with "may be recommended". Please add a statement like: "the clinical impact of these findings should be subject to further trials"

Abstract changed to reflect these comments

Methods:
I did not find the surgical team and the table carrying the surgical instruments in your model which might interfere with airflow. The model might therefore not correctly reflect the reality during surgical procedures.

We agree that a myriad of factors appear to affect the system (lights, mayo stands, personnel, draping, etc…). That is why we took a conservative approach and introduced as few flow obstructions as possible into the ventilation environment, since each flow obstruction creates a localized ventilation disturbance that can aid in hot-air convection current formation. Thus, we would expect the effects of patient warming excess heat to be magnified with the addition of a surgical team and instrument trays. As such, we felt the simplicity of our chosen configuration would allow our result to have as broad of an interpretation as possible and be more generalizable across a range of surgical procedures.

Why did you perform two runs and not more for each experimental factor? Can you provide a statistical reason?

The reasons are twofold. First, a similar study conducted in the UK1 employed the same study design/methods (2 runs) and was found to be sufficiently powered since it rejected the null hypothesis. Thus, we would expect a similar degree of power in the present study, which was confirmed since we rejected the null hypothesis.

Second, powering for generalized linear models can be a bit complicated, but we can take a quick look at the study power we attained with the present design (3121, n=2 replicated) for an additive Poisson model with overdispersion having no drape effect, where log(mu)=B0 +B1Icontrol+ B1ICFW. Thus, the test of interest is the value of B1 since it compares the difference between forced air warming and conductive fabric warming. We further assume: dispersion parameter=13, Mean count Conductive Fabric Warming=2, Mean Count Forced Air Warming=X, 1-tailed test with alpha=0.05. Here is a table of study power for B1 based on X (the mean forced air warming bubble count).

Mean of Forced Air Warming Count (X)Power
200.5308403
400.7416874
600.8364269
800.8875179
1000.9183041
1200.9382903
1400.9519824
1600.9617534

Given that our observed realization of X was 132.5, the study was sufficiently powered (i.e. around 95%).

1. McGovern PD, Albrecht M, G Belani K, Nachtsheim C, Partington PF, Carluke I, et al. Forced-air warming and ultra-clean ventilation do not mix: An investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics. J Bone Joint Surg Br. 2011 Nov;93(11):1537–44.

Page 7, lines 14-19: Did you fix the forced-air blanket according to the manufacturer's instructions? Please state.

Yes, the forced air warming blanket was adhered to the mannequin for each run.

Results:
Page 9, line 34 Examining Fig. 4, I have the impression that there might be a huge inhomogeneity between the two runs during forced-air warming (at high drape height this observation seems to be even more evident). Why did you not perform more runs (see comment in the "methods" section)?

This inhomogeneity was accounted for in the model by using a dispersion parameter. Also, the study was sufficiently powered as previously stated using 2 runs. Further, the observed degree of over-dispersion was not unexpected and within the norms that occur when modeling count data (see Faraway chapter 3 for a general reference and example).1

1. Faraway JJ. Extending the Linear Model with R: Generalized Linear, Mixed Effects and Nonparametric Regression Models. 1st ed. Chapman and Hall/CRC; 2005. 312 p.

Discussion:
Page 11 lines 44-49 Here you state that personnel working in the OR might influence air flow, but you do not consider this in your study design.

In addition to personnel, there are a range of factors that are likely to influence air flow (lights, mayo stands, draping, etc…). That is why we took a conservative approach and introduced as few flow obstructions as possible into the ventilation environment, since each flow obstruction creates a localized ventilation disturbance that can aid in hot-air convection current formation. Thus, we would expect the effects of patient warming excess heat to be magnified with the addition of a surgical team and other flow obstructions. As such, we felt the simplicity of our chosen configuration would allow our result to have as broad of an interpretation as possible and be more generalizable across a range of surgical procedures.

Page 15 Please delete the last sentence. See also comment to page 3 lines 51-54.

Last sentence modified. Trial had no pollution or clinical based endpoints, so we agree that no statement can be made about the clinical risks of forced air.

Reviewer #3:
Substance:
Title:
"Excess Heat" - this does not seem to encapsulate what you are trying to say. Any heating technique has "excess heat" - even the "thermally efficient ?. conductive fabric" which is mentioned in the accompanying letter, releases excess heat. All the outsides as well as the sections not in direct contact with the patient, releases excess heat.

We, also, struggled to come up with a “term” describing the thermal energy not absorbed by the patient and released into the ventilation environment. We actually tried terms like “waste heat,” but felt that such a description was negative and implied no beneficial therapeutic purpose related to its existence. So, we picked another imperfect term “excess heat” because at least such a description implies that it is a by-product of a useful therapy. If you have any suggestions, we would certainly be willing to consider them.

" ventilation" - most anesthesiologists associate "ventilation" with the ventilator and the lungs, rather than as OR ventilation. Suggest that OR ventilation and/or air currents be clearly indicated in the title.

Agreed, changes made.

Abstract:
Paragraph 1, last line: the word theater is used. Typically, the USA uses OR.

Noted and changed in manuscript.

Introduction:
Page 4, Lines 24-26 " Recently, ?. Shown no infection reduction benefits"
This thought needs to be expanded in the Discussion. Why do these articles show no benefit, while the present article seems to have the/an answer.

See lengthy response to Reviewer #1's similar question. The short answer is that we do not have the answer, but instead have noticed an association that could be an important piece of the puzzle at hand regarding the failure of laminar flow in modern surgery.

Page 4, lines 50-52: " excess heat naturally rises ?"
There is no discussion here of the effect of the "forced air", i.e. the blower creating air currents - this is not only a passive process. There is also no mention of the speed at which the "bubbles" exit the generating device.

We agree that forced air warming is not a passive process and involves bulk airflow. However, the distribution of the heated air is through a coverlet that acts as a diffuser and greatly reduces the velocity of the heated airflow upon release. Thus, it is the thermal energy of the vented air and not the bulk airflow velocity that influences convection current formation.

The "bubbles" exiting the generating device are slowed to a near stand-still upon exit by a diffuser cone (visible in the pictures). The diffuser cone increases the conical exit diameter from a 0.4 inch delivery tube to a 2.3 inch diameter exit nozzle, thus, increasing the cross sectional area by a factor of 33 times.

Page 4, lines 52-57: " ? ventilation disruption is proportional to the amount of excess heat.."
This is a very strong statement, and is also a main thesis of this article - this certainly needs to be well and strongly referenced

Recent research, accepted on October 14 in Anaesthesia (British journal),1 investigates the thermal basis of ventilation disruption due to patient warming excess heat. The reference for this article has been added to support the statement.

1. Dasari K.B, Albrecht M, Harper M. Effect of forced air warming on operating theatre laminar flow ventilation performance. Anaesthesia. 2011 "In Press (accepted October 14th, MS# 6983)".

Methods:
Page 6, lines 31-34 : " neutrally buoyant detergent bubbles ?. 4 mm ?. diameter" - there needs to be specific mentioning about the size of potential bacterial contaminations, as well as the weight, and density of such presumed contaminants. There seems to be a huge size discrepancy.

There are two forms of pathogenic organisms commonly found suspended in OR air: 1) free floating bacteria (0.5um to 4um in size),1 and 2) desquamated skin flakes that act as bacteria carrying fomites (ranging from 5um to 33um in size, with a median of 20um).2 The settling time for these particles is dependent upon their size. For example, in still air the time it takes an ideal aerosol particle to settle 5 feet is 41 hours for a 0.5um sphere, 12 hours for a 1um sphere, 1.5 hours for a 3um sphere, 8.2 minutes for a 10um sphere, and 5.8 seconds for a 100um sphere.3 Of course, in turbulent regions these particles will remain suspended for longer periods of time.

Thus, the use of neutrally buoyant bubbles mimics the movements of the smaller particles (those less than 10 to 20um) suspended in ORs. This is because the neutrally buoyant detergent bubbles have an infinite settling time and, therefore, have similar flow characteristics to the smaller particles.

Details added to discussion section addressing this point.

1. Jensen PA, Schafer MP. Sampling and characterization of bioaerosols. NIOSH

manual of analytical methods. 1998;:82–112

2. Mackintosh CA, Lidwell OM, Towers AG, Marples RR. The dimensions of skin fragments dispersed into the air during activity. J Hyg (Lond). 1978 Dec;81(3):471–9.

3. for a general reference on settling times see several articles in http://www.cdc.gov/niosh/topics/aerosols/

Page 6, lines 43-45: " ? validated for the visualization of air currents ?"
There still seems to be a step needed here to go from "air currents" to carrying of very small (even microscopic) potential, contamination particles.

It depends upon the settling time of the particle. Those with slow settling velocities (less than 10 to 20um) easily follow weak air currents, whereas larger particles do not. Comment added to discussion section.

Page 7, line 4 " An anesthetist ? stood motionless ?"
According tot the two pictures (not taken from exactly the same perspective, it does not seem that the human was in the same position. The position of the head of the anesthetist is also not the same.
It is also not possible to see from the pictures if the clear plastic section of the forced air blanket was covering the head of the mannequin.

The camera perspectives were changed slightly between the photographs to better capture the movement of the tracer bubbles for the convection current photographs only. In hindsight, this might not have been the best practice since it gives the impression of differing setups during the formal "count" experiments. The setup was not substantially different during the formal "count" tests (i.e. surgeon stood in the same location, at the same angle, bubble diffuser laid down on OR head rest and directed into drape, etc…). Also, the plastic drape was extended over the head of the mannequin.

Page 7, line 16-17: " ? the device was INTRODUCED under the drape ?"
We do not know how far down on the chest the device actually was. If the device was placed relatively high on the chest, there would be significant amounts of forced air being blown around the head of the mannequin.

The device was affixed with the blanket adhesive to the waist of the mannequin per normal operative setup for total knee replacement. Additionally, based upon our observations the upward movement of the hot exhaust was not due to "jetting" off of the blanket, but instead due to the bulk upward movement of the "still" heated air that collected under the drape. This hot exhaust tended to move towards the head end of the drape because it was the most elevated escape point. Thus, if the hot exhaust were even introduced at the foot end of the mannequin, it would very likely be detected exiting at the head end of the drape.

Results
Page 9, lines 19-20: " ? the variance is greater than the mean ?"
The authors needs to convince the reader that this variability is not due to experimental variation, e.g. the distance of the anesthetist to the OR table, the angle of the bubble device, etc. It is essential that the equipment be totally "fixed", and not placed in a position that the authors "think" was what was done last time. This is especially true, given that there is a strong potential for conflict of interest, and unconscious bias needs to be seen to be minimized.

It is unlikely that the elevated variance of the count was a product of unrepeatable experimental technique, but instead just a property of Poisson modeling. Many, perhaps most, Poisson models for count data are overdispersed when there is a perfectly valid and repeatable experimental setup. The overdispersion comes from the idea that we are using a model to approximate a real world phenomenon that doesn't exactly follow any defined distribution. As such, most statistical models where the mean and variance are linked (i.e. Poisson, logistic, etc…) commonly employ an added dispersion parameter. This is in contrast to the normal model, which is rather unique

since it naturally has a dispersion parameter (sigma) and the mean (mu) and variance (sigma) are unlinked. Thus, the use of an added dispersion parameter allows the Poisson model to follow the more common conventions of the normal model that most researchers are familiar with.

In terms of ensuring consistent setups between experiments, the following was done: 1) the exact drape height for low and high was marked on the IV poles; 2) there were visible marks on the abdomen of the mannequin where the forced air torso blanket was to be affixed; and 3) the bubble generator was laid down on the head rest of the OR table in the same location during the formal experiments where counting was performed to ensure a consistent setup. The bubble generator was only hand held during the photographs shown in figures 5 and 6, which are for display purposes. It was necessary to move the bubble generator around to get a clear photograph of the effect in those situations.

Page 9, lines 60-61: Figure 5
It is not possible to see which direction the opening of the bubble generating device is pointing - given the sensitivity of air flows, it is expected that even a tiny superior elevation might have major effects on air current flows.

During the formal count experiments, the bubble generator was laid down on the OR head rest of the table and aimed into the drape. Comment added to manuscript to reflect this setup detail.

Page 10, lines 4-7: " ? upwards and over the topside of the anesthesia drape ?"
I am surprised that the bubbles move towards the direction of the center of the room. Most of the laminar air flow is generated in the center of the room, and air currents should be flowing from the middle to the periphery.

Such effects are created by a combination of the surgical drape and lighting disturbances, both of which create “wakes” that draw the bubbles towards the center of the room. It is a rather complex phenomenon that we, initially, did not expect… at least until we observed the localized flow disruptions associated with the lights, drapes, and personnel.

Page 10, lines 9-10: " ? an overhead surgical light had a significant impact ?"
As mentioned in the literature list, overhead equipment does have a significant effect to disrupt the designed downwards laminar flow rate. Figure 5 show the overhead OR light very close to the head of the bed. Most surgeons would not select that position for knee surgery. It might be a good idea for the authors to provide a diagram of each and every piece of overhead equipment that might disrupt the laminar airflow, and clearly indicate why that position was selected. As mentioned before, the readers need to be convinced that there is no bias, especially no unconscious bias.

The full experimental setup is clearly shown in Figure 1, along with exact lighting placement. The lighting placement was decided by the orthopedic specialist in our research group whom participated in the experiment (Paul McGovern). Paul is 6' 3" tall (much taller than most), which probably dictates the need for the forward placement of the light towards the anaesthesia drape. This was to allow his head a clear range of motion and provide a space in which to stand during the operation. Not sure what, if anything, needs to be added to the manuscript. We placed a comment in the manuscript that the lights were setup for a “tall surgeon.”

Discussion:
Page 11, lines 24-29: " ? mobilize airborne bacteria ?"
As mentioned before, the line/connection from 4 mm bubbles to airborne bacteria has not been drawn by this research, nor from the literature.

Agreed, statement changed in the manuscript to more accurately reflect the potential for ventilation disruption, since we did not study any pathogen based endpoints.

Pages 12, 13, 14: Most of the discussion on these pages is about the risk of infection. This study is about 4 mm diameter bubbles that potentially move over the drapes.

There is no proof from this study that the sizes of bacterial contamination would follow this pathway.
Therefore, the strongest conclusion from this study is that " 4 mm diameter neutrally buoyant bubbles, under out specific experimental conditions, with a very high variance, go over the drapes."
I would strongly urge the authors to refrain any stronger claims based on this study, and remove most/all of the discussion of infection risk (including the references which do not pertain directly to this study.) In future studies, it could be mentioned that the line/pathway from 4 mm bubbles to infection sized particles be studied.

Agreed, changes made to discussion to reflect that this study assessed ventilation air current disruption, not pathogen mobilization.

Page 15, lines 4-19 : this is a very reasonable conclusion - see previous comment.

References:
Please indicate what has happened to reference 17 "in press"

This article was published November 1st in the British journal of bone and joint surgery.

Figures:
Figure 1: it seems that there is a device on a stand. Was the camera also on a stand to ensure a consistent position? Were all other devices maintained in exactly the same position?

Yes, the position of all devices was marked with tape on the floor to ensure repeatable placement of the experimental equipment.

Figure 2: What was the exit rate of flow of the bubbles? Could this have interacted with the air flow from the forced air devices?

The exact flow rate is unknown (there is no easy way to measure this), but the diffuser slowed the exit of the “bubbles” to a near stand-still and, thus, had no effect on the airflow currents in the room. See previous comment addressing this above.

Figure 5: Note the position of the head of the anesthetist - looking straight ahead. Also note how close the person is standing to the OR table. We cannot see the opening of the bubble device, nor can we see if the upper portion (clear plastic section) of the forced air device was covering the head of the mannequin.

The plastic sheet was covering the head of the mannequin; however none of our pictures capture this for they were, unfortunately, aimed elsewhere. The distance between the person and the drape was not as carefully controlled for these photos (given that they were done just to demonstrate the effect) as it was for the formal experiment when the counts were performed. Also, the bubble wand was moved about to best demonstrate the effect for the photograph. This was not the case during the formal count experiment.

Figure 6: Note the person's head is now looking down.

Again, the position of the anesthesiologist was not carefully controlled during these demonstration photographs.

Style:
Abstract:
Paragraph 1, last line: the word theater is used. Typically, the USA uses OR.

Agreed, changed

Page 5, line 21-22 - again the use of the word theater

Changed

Page 6, line 20-23: it might be interesting for the readers to be made aware of the

	number of air changes per hour for normal rooms Conventional ventilation environments require a minimum of 15 air changes per hour. This detail was added to the manuscript. Methods: Page 8, line 34-37 - the $p<0.05$ is typically mentioned at this point Detail added Page 7, line 4 " An anesthetist ? stood motionless ?" In the USA, anesthetist typically refers to a CRNA, rather than an anesthesiologist. Changed to anesthesia provider.

Click here to download Supplemental Data File (.doc, .tif, pdf, etc.): response to reviewer comments-2.docx

Patient Warming Excess Heat: Effects on OR Ventilation Performance During Total Knee Replacement

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Abstract

Background: Patient warming has become a standard of care for the prevention of unintentional hypothermia based upon benefits established in general surgery. However, these benefits may not fully translate to contamination sensitive surgery (i.e. implants), for patient warming devices release excess heat that may disrupt the intended ceiling-to-floor ventilation airflows and expose the surgical site to added contamination. Therefore, we studied the effects of two popular patient warming technologies, forced air and conductive fabric, versus control conditions on ventilation performance in an orthopedic operating room during a simulated total knee replacement.

Methods: Ventilation performance was assessed by releasing neutrally buoyant detergent bubbles ("bubbles") into the non-sterile region under the head-side of the anesthesia drape. We then tracked whether the excess heat from upper-body patient warming mobilized the "bubbles" into the surgical site. Formally, a randomized replicated design assessed the effect of device (forced air, conductive fabric, control) and anesthesia drape height (low-drape, high-drape) on the number of "bubbles" photographed over the surgical site.

Results: The direct mass-flow exhaust from forced air warming generated hot-air convection currents that mobilized "bubbles" over the anesthesia drape and into the surgical site, resulting in a significant increase in bubble counts for the factor of patient warming device ($p<0.01$): forced air had an average count of 132.5 versus 0.48 for conductive fabric ($p<0.01$) and 0.01 for control conditions ($p<0.01$) across both drape heights. Differences in average bubble counts across both drape heights were insignificant between conductive fabric and control conditions ($p=0.87$). The factor of drape height had no significant effect ($p=0.94$) on bubble counts.

Conclusions: Excess heat from forced air warming represents a significant ventilation disruption concern during orthopedic surgery. The use of thermally efficient patient warming devices (i.e. conductive) – those that minimize excess heat release – may be preferable for contamination sensitive surgery. The clinical impact of these findings should be subject to further trials involving infection-based endpoints.

Number of words: 315 of 400

Introduction

Operating room (OR) ventilation has been recognized, historically, as an important component of a multi-faceted infection reduction strategy in orthopedics. Starting with the work of Sir John Charnley in the 1960's,[1] twenty-years of research established the benefits of using sophisticated ventilation systems to create localized zones of highly-filtered air over the surgical site. Clinically, these systems were shown to reduce surgical site microbial exposure[2] and led to the United Kingdom commissioning the first and only randomized clinical trial, which demonstrated a significant reduction in orthopedic infection rates.[3] Recently, though, a number of national studies have shown no infection reduction benefits.[4-6] These results question the value of sophisticated ventilation systems. Although the cause for such failures is presently unknown, changes have been made to OR equipment that may affect ventilation performance; notable among them the introduction of forced air patient warming in the 1990s.

Patient warming is a recognized and necessary standard of surgical care, with warmed patients having better outcomes through reduced blood loss, improved wound healing, reduced duration of hospital stay, improved survival, and reduced surgical site infection rates for dirty surgery (colorectal).[7,8] However, patient warming systems incidentally release excess heat that is not absorbed by the patient. This excess heat naturally rises and may disrupt the intended ceiling-to-floor OR ventilation airflows. Thus, potential for ventilation disruption is proportional to the amount of excess heat emitted, which depends upon the choice of patient warming technology.[9]

Two general classes of patient warming technology are used intraoperatively. The first, forced air, warms by distributing heated air (43°C) under the surgical drapes and over the patient in a large envelope.[10] The second, conductive blankets, uses a resistive heating element to directly apply heat to the patient's skin.[11] Since conductive blankets are localized in their application, they tend to have higher thermal efficiencies and contribute less excess heat to the environment than forced air.[12] Therefore, in this study we chose to evaluate the effects of both patient warming technologies versus control (no warming) on ventilation performance. The study was conducted in a standard orthopedic OR having ceiling-to-floor displacement ventilation during a mock knee replacement surgery with upper-body warming. Changes in ventilation airflow patterns were assessed using neutrally buoyant detergent bubbles.

Methods

Operating Theater Characteristics:

Experiments were carried out in downward displacement ventilation OR used for orthopedic surgery at the University of Minnesota Hospital (Minneapolis, MN). Ceiling-to-floor airflows are generated by a grid of diffuser panels over the OR table, each of which contains a final point of use high efficiency particulate air (HEPA) filter. Supply air is centrally pressurized, pre-filtered, and then ducted to the individual ORs. The OR utilized for these experiments received a supply airflow of 1819 ft^3/min, resulting in 19.7 air changes per hour; minimum requirements for hospital ventilation require 15 air changes per hour.[13] Airflow balance is certified yearly. Surgical lighting was provided by two Chromophare D650 Plus over head lights (Berchtold Corporation, Charleston, SC).

Airflow Visualization Procedures:

High intensity lighting was used to illuminate neutrally buoyant detergent bubbles having a 4 mm average diameter (referred to herein as "bubbles"). "Bubbles" were produced by a generator (Sage Action, Ithaca, NY), which utilized a helium air supply and detergent. The equipment filters the bubbles using a centrifugal classifier that only allows bubbles of neutral buoyancy to pass – those heavier or lighter are discarded. The bubble generator is specifically designed and validated for the visualization of air currents.[14] For photography, a digital camera (500D, Canon, Surrey, UK) was employed and shutter exposure time was set to ¼ of a second for time-lapsed-photography.

Total Knee Replacement Experimental Setup

A mannequin was laid in the supine position and draped in accordance with the standard draping protocol used by the hospital for knee replacement procedures. A perforated drape was used for the proximal limb, with a sterile stocking for the foot and distal limb. (**Fig 1**). An anesthesia provider dressed in surgical scrubs stood motionless at the head end of the table behind the anesthesia/surgery drape. The anesthesia/surgery drape was either: 1) clipped to intravenous (IV) poles and raised 0.75 meters above the operating table (high-drape); or 2) clipped to IV poles and raised 0.25 meters above the operating table (low-drape). The upper-body warming device was introduced under the drape and was either: 1) a torso forced air blanket (Bair Hugger Model 540, Arizant Healthcare, Eden Prairie, MN); 2) a torso conductive fabric blanket (Hot Dog Model B110, Augustine Temperature Management, Eden Prairie, MN); or 3) no warming device (control). The blankets were powered by standard controllers set to 43°C (forced air - Model 750, Arizant Healthcare, MN; conductive fabric - Model WC02, Augustine Temperature Management, MN). "Bubbles" were introduced at the head/neck of the mannequin to track under-drape resident air movements in the region where the excess patient warming heat was being released. To ensure a consistent release point and direction for the bubbles exiting the generator, the diffuser cone was laid down on the OR head pad and aimed directly into the drape (perpendicular to the raised drape edge).

Sampling Procedures

Bubble counts over the surgical site were measured using a sequence of ten photographs taken at ten-second intervals. The number of bubbles reaching the surgical site was determined by counting the number of bubbles intersecting a vertical light curtain in a 0.75 by 0.75 meter region directly over the surgical site (**Fig 2**). Additionally, time lapse

photography was performed to provide directional information on airflow patterns not captured in bubble count data.

Experimental Design

A replicated (n=2) $2^1 3^1$ full factorial design was employed to assess changes in bubble counts over the surgical site. The experimental factors considered were: 1) anesthesia screen: low-drape or high-drape; and 2) patient warming device: conductive fabric, forced air, or no warming device (control).

Statistical Analysis

A Poisson regression model for over-dispersed data was fit having the sum of bubble counts for each experimental run (10 pictures) as the response and the factors identified in the experimental design as predictors plus an interaction term. A log-likelihood ratio test was used to determine the significance of the interaction term by comparing the full model versus an additive model with adjustment for over-dispersion; if the interaction term was insignificant, a second set of tests for each additive parameter was performed using a log-likelihood ratio test comparing the parameter deleted additive model versus the full additive model with adjustment for over-dispersion. Reported means and standard errors were computed using maximum likelihood parameter estimates and contrasts assuming asymptotic normality (Wald tests). *P*-values correspond to 2-tailed tests and *P*-values<0.05 were considered significant.

Results

Bubble Counts Over the Surgical Site:

In viewing the raw bubble count data (**Fig 3**), it is apparent that there is a large increase in the number of bubbles reaching the surgical site when forced air warming is in use versus either conductive fabric warming or control conditions. Further, this increase appears to be independent of drape height. The data, moreover, appears to be over-dispersed for a poisson count model (i.e. the variance is greater than the mean). As such, adjustment for over-dispersion in the model appears warranted.

Formal inference using poisson regression (Table 1) revealed the only significant factor affecting bubble counts to be patient warming device ($p<0.001$); the factors of drape height ($p=0.937$) and the interaction term between drape height and patient warming device ($p=0.980$) were insignificant. With the full additive model (**Fig 4**), the use of forced air warming was found to result in a predicted mean sum of bubble counts equal to 132.5 when averaged across both anesthesia drape heights; such a count represents a significant increase in the number of bubbles reaching the surgical site versus both conductive fabric warming ($p=0.003$) and control conditions ($p=0.008$), which had predicted mean sum of bubble counts equal to 0.48 and 0.01, respectively. Moreover, differences in the number of bubbles reaching the surgical site were not significantly different between conductive fabric warming and control conditions ($p=0.865$).

Time Lapse Photography:

With forced air warming, convection current formation was detected in the space between the anesthesiologist's body and anesthesia drape (**Fig 5**). These convection

currents were observed to mobilize resident air near the mannequin's head upwards and over the topside of the anesthesia drape, which then spilled into the surgical site. Further, the presence of an overhead surgical light had a significant impact on the dynamics of these convection currents; the recirculation zone extending below the light tended to magnify resident air mobilization into the surgical site by re-directing the upward convection currents into the light's "flow-shadow" and over the surgical site. As a note, the surgical lights were not moved over the course of the experiments and their setup is clearly displayed (**Fig 1**).

In contrast, convection currents were not detected with conductive fabric warming (**Fig 6**) and, therefore, there was no apparent upward mobilization of resident air. Instead, ventilation airflows were observed to follow the intended ceiling-to-floor path, sweeping contaminants down and away from the surgical site. Time lapse photography of control conditions looked identical to those recorded with conductive fabric warming and, as such, are not displayed separately.

Discussion

This study sought to evaluate the effects of patient warming excess heat - using two fundamentally different technologies: forced air and conductive fabric - on OR ventilation performance during total knee replacement. Forced air warming was found to have a significant disruptive impact on clean-airflow patterns over the surgical site, whereas conductive fabric warming had no noticeable effect versus controls. Moreover, forced air warming was found to establish convection currents that mobilized resident air from non-sterile areas (under the anesthesia drape) upwards and into the surgical site. The clinical concern is that convection currents may mobilize under-drape contaminants into the surgical site and/or impede the ventilation systems ability to clear contaminants from the surgical site. These concerns are most relevant for smaller airborne particles ≤10μm, such as free-floating bacteria[15] and skin cell fragments,[16] having similar airborne characteristics to the neutrally buoyant detergent bubbles studied (i.e. appreciable suspension times).

The buoyancy-driven convection currents appeared to form in regions of localized ventilation disturbance due to surgical lighting, drapes, and personnel. For example, past research has identified surgical lighting to be a significant source of ventilation disruption through the downstream wake and concomitant recirculation zone.[14] In the present study, we were able to visualize this recirculation zone using "bubbles" and found it to extend approximately 1 meter below each light. Such disruption was further magnified by the presence of a raised anesthesia drape, which created a still zone by blocking the natural passage of air out of the ventilation field. Lastly, the presence of an

anesthesiologist behind the anesthesia drape added a final flow obstruction[17] and, ultimately, created a channel behind the drape in which ventilation airflows were nearly quiescent. Under these fragile conditions, the mass-flow of forced air warming exhaust was sufficiently buoyant to push upward, over the top drape edge, and into the surgical site.

It is worth mentioning, however, that the observed disruption was dependent upon our exact setup (i.e. arrangement of draping, lights, and personnel), which was dictated by traditional clinical practice and some basic considerations. For example, we eliminated the presence of a surgical team and instrument trays, both of which were likely to increase ventilation disruption. Thus, our results should generalize to any surgical team/instrument tray configuration using our arrangement of lighting and drapes within a similar ventilation system. It should be noted that the head-end surgical light was positioned close to the raised anaesthesia drape. This placement was due to the height of our surgeon (6 foot 3 inch), whom needed head-room to operate. Thus, for shorter surgeons different results might be expected. Lastly, it was necessary to turn surgical lights off during the experiment to allow for consistent "bubble" counts in the intersecting light-plane. Given that lighting heat sources tend to adversely affect ventilation performance,[14] our results should be considered conservative in nature.

The most recent articles published on the association between patient warming excess heat and ventilation disruption present contradictory conclusions. Two studies conducted in the United Kingdom have characterized both the thermal basis[9] and airflow patterns[18]

supporting the physics behind ventilation disruption in laminar flow ORs. Further, the latter study found a significant association between the use of thermally inefficient patient warming systems (i.e. forced-air) and deep joint infection rates during hip and knee prothesis.[18] In contrast, a published study in the Netherlands[19] found no evidence of ventilation disruption due to forced air excess heat when evaluated with the DIN 1946:2008-12 standard.[20] This discrepancy in findings is likely related to two primary differences in test methods.

First, the surgical lights were positioned in-line with the OR table in both of the United Kingdom studies based upon common clinical practice, whereas the lights were positioned to the sides of the OR table in the Netherlands study. Second, the United Kingdom study assessing airflow patterns evaluated the effect of patient warming excess heat on interior particle loads - defined as neutrally buoyant bubbles released 1) near the surgeon at floor level and 2) under the anaesthesia drape at the head of the OR table. With the Netherlands study, it is unclear whether the protective effect was assessed for outside particle loads (particles released on the periphery of the ventilation boundary) or inside loads (particles released by the surgeon). The DIN 1946:2008-12 standard requires testing and reporting of both types of particle challenge - yet the authors reported only one set of results and no information is given as to which test the results correspond to.

Considering the wide-spread adoption of forced air warming in clinical practice, it is interesting to note that over the past 10 years national studies have failed to detect the

infection benefits of laminar flow versus conventional ventilation systems during orthopedic joint replacement surgery.[4-6] Moreover, one of these national studies found significantly higher infection rates in the laminar flow theaters versus its conventional counterparts.[6] The likewise disruption of both laminar flow and conventional ventilation due to forced air warming may be the explanatory factor, since historical studies on laminar flow ventilation conducted before the introduction of forced air warming showed clear infection reduction benefits.[3]

It, therefore, appears that further research is warranted with infection based endpoints (airborne bacteria, fomites, and/or joint sepsis rates) to characterize the clinical risks of forced air warming ventilation disruption. Preferably, this research would be conducted on a national basis covering orthopedic operations in both laminar flow and conventional ventilation environments. Thus, we suggest the use of thermally efficient patient warming devices for contamination sensitive surgery, pending the results of clinical trials that characterize the clinical risks of forced air warming excess heat.

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Figure Legends

Figure 1: Total knee replacement setup showing: (A) High anesthesia drape position; and (B) low anesthesia drape position.

Figure 2: 1) Definition of count region above the surgical site (dashed lines) showing neutrally buoyant detergent "bubbles", which appear as white dots (A) when they intersect the vertical light plane. 2) View of "Bubbles" exiting the diffuser end in still air.

Figure 3: Bubble counts over the surgical site for each photograph (data is jittered to avoid overprinting). 10 photographs were taken for each experimental run.

Figure 4: Predicted mean sum of bubble counts (±Standard Error of the Mean). Predicted means and standard errors were computed from the full additive model with adjustment for over-dispersion.

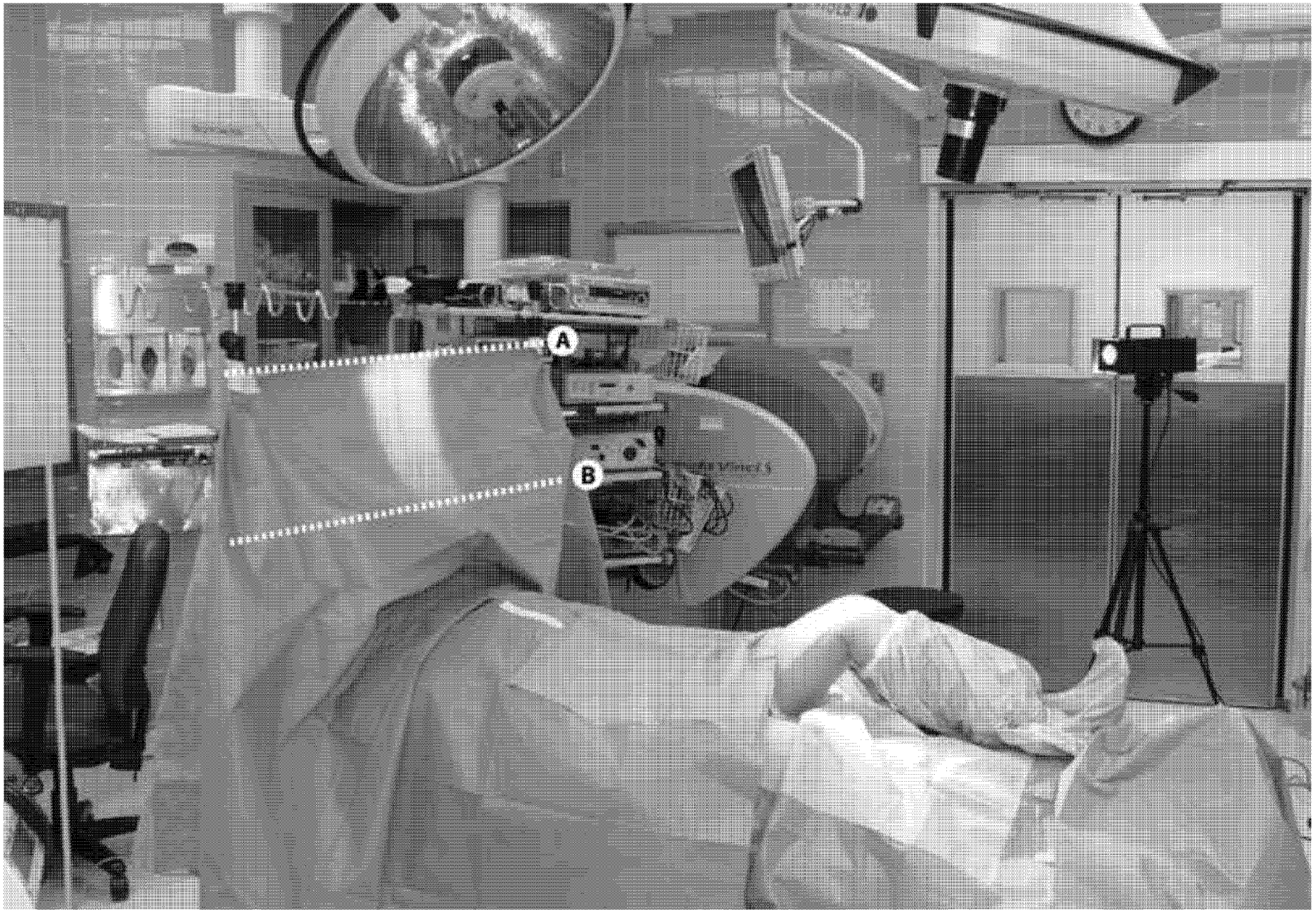
Figure 5: Time lapse photography of forced air warming showing upward mobilization of neutrally buoyant detergent bubbles due to hot-air convection currents. Note: Bubble diffuser was moved from the experimental position (laid-down on OR table) to better illustrate the effect for photography.

Figure 6: Time lapse photography of conductive fabric warming showing no noticeable effect on ceiling-to-floor ventilation airflows (i.e. the neutrally buoyant detergent bubbles are swept down and away from the surgical site). Control conditions looked identical and, thus, are not shown separately. Note: Bubble diffuser was moved from the experimental position (laid-down on OR table) to better illustrate the effect for photography.

Table 1: Poisson bubble count model parameters and their significance.

Model Parameter	***p*-value**
Drape Height*	0.937
Patient Warming Device*	<0.001
Drape Height X Patient Warming Device**	0.980

* Computed using likelihood ratio deleted parameter tests from the additive model
** Computed using a likelihood ratio comparing full and additive model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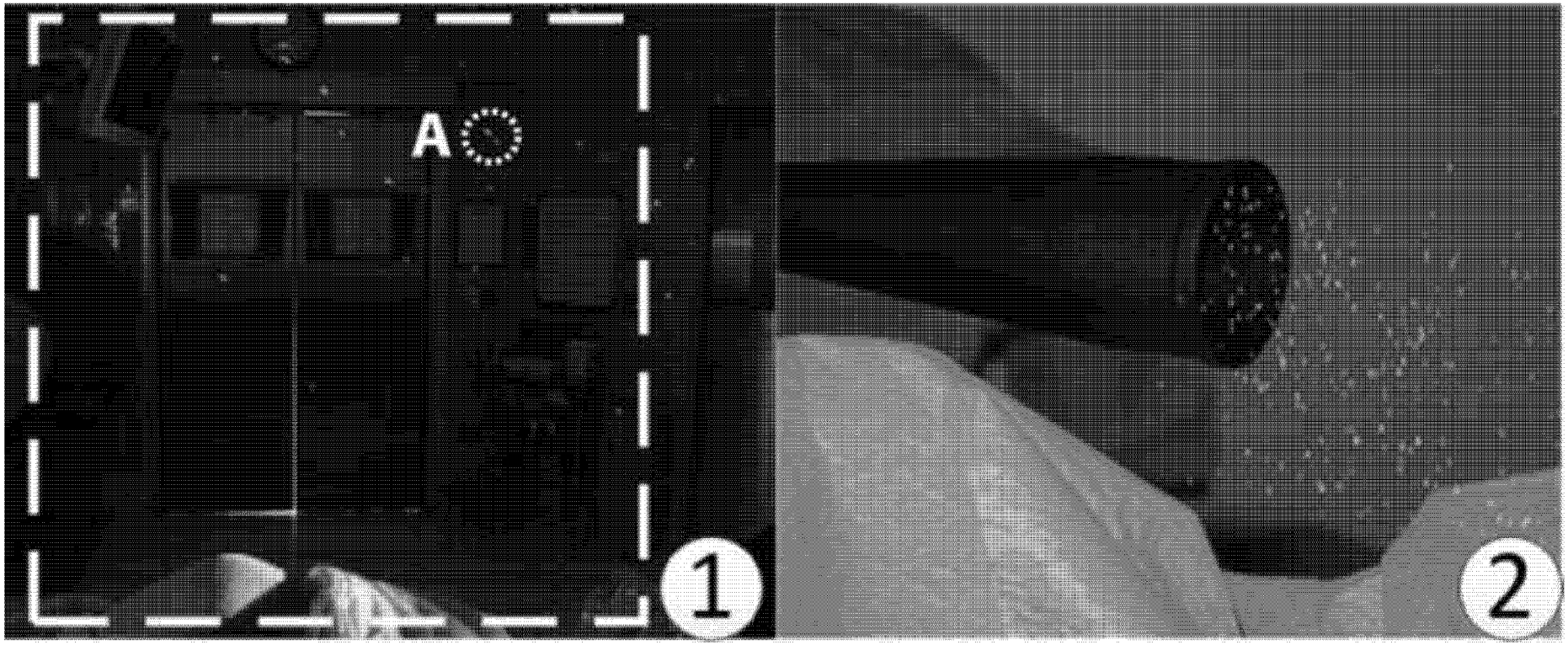
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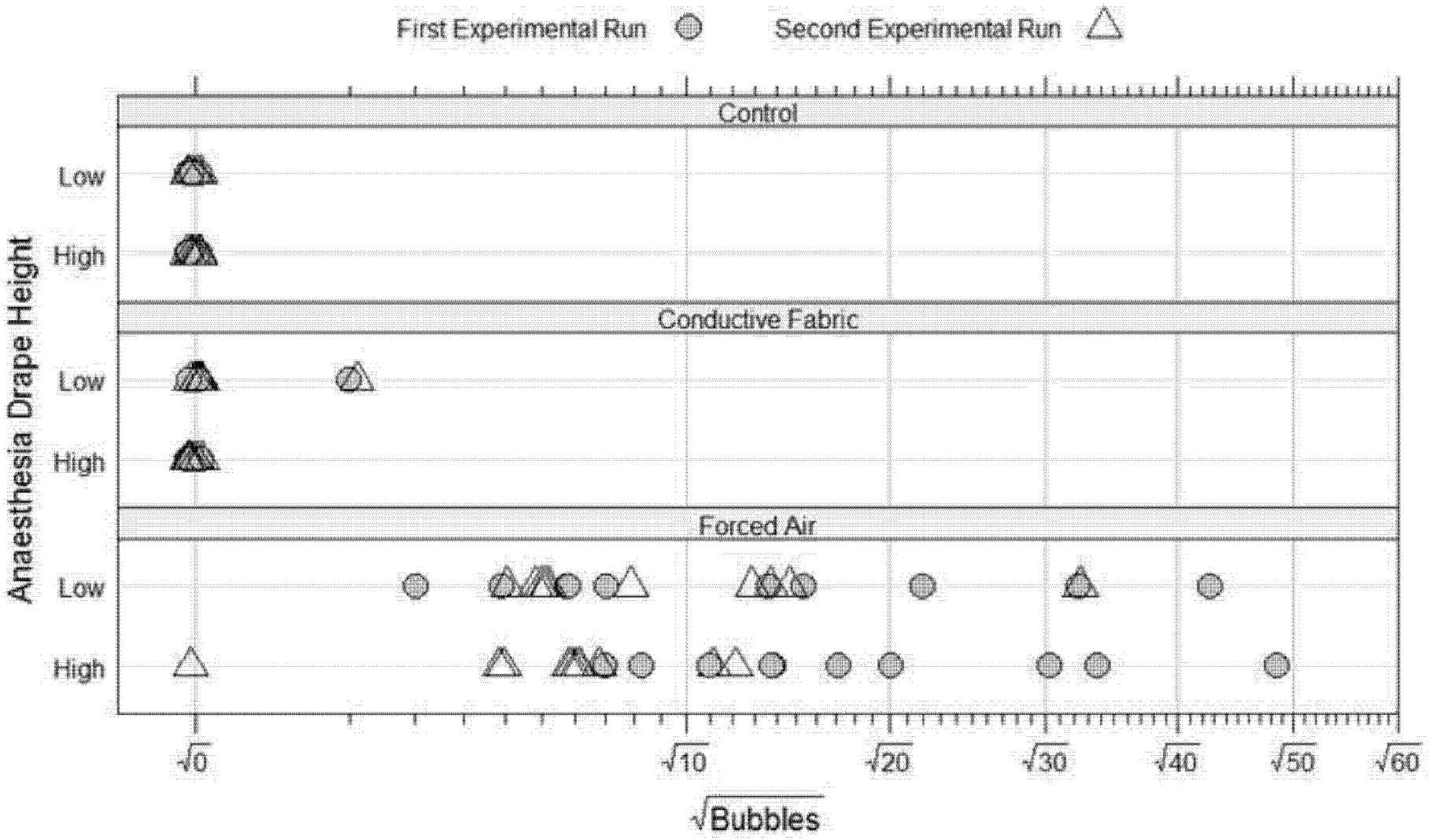
First Experimental Run
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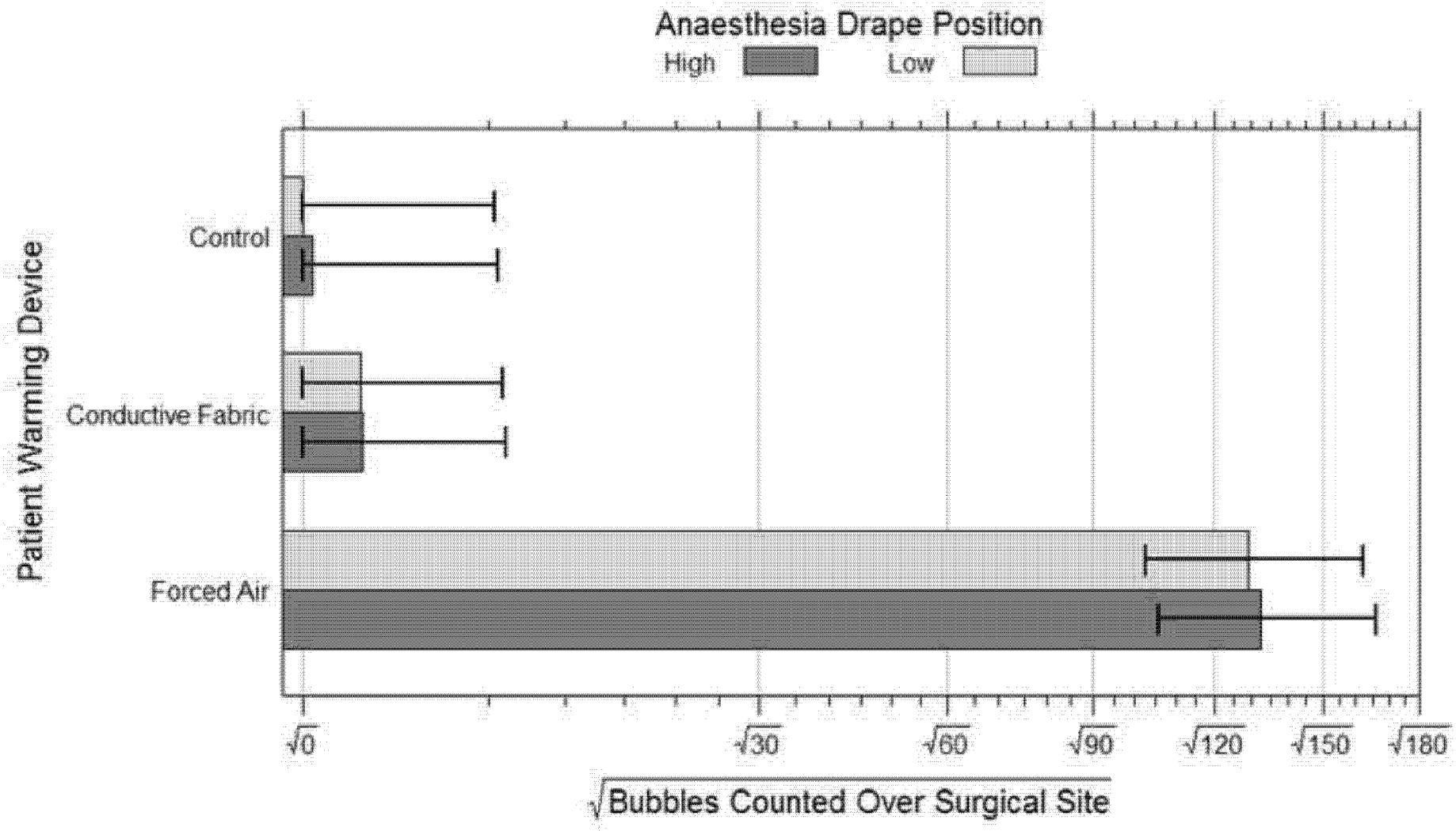
Anaesthesia Drape Position
High
Low
Patient Warming Device
Control
Conductive Fabric
Forced Air
√0
√30
√60
√90
√120
√150
√180
√Bubbles Counted Over Surgical Site